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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/573,944

03/14/2007

Judith A. Varner

UCSD-10834

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MEDLEN & CARROLL, LLP
101 HOWARD STREET
SUITE 350
SAN FRANCISCO, CA 94105

EXAMINER

BELYAVSKIY, MICHAIL A

ART UNIT

PAPER NUMBER

1644

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/573,944	Applicant(s) VARNER, JUDITH A.	
	Examiner MICHAEL BELYAVSKYI	Art Unit 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 June 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) 23-31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-22, 32 and 33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1644

RESPONSE TO APPLICANT'S AMENDMENT

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 06/11/10 has been entered.

Claims 1-33 are pending.

2. Claims 23-31 stand withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b) as being drawn to nonelected inventions.

Claims 1-22 and 32,33 read on a method for altering the level of hematopoietic progenitor cell adhesion to target tissue comprising using an agent that alters specific binding of intergrin $\alpha 4\beta 1$ to an intergrin $\alpha 4\beta 1$ ligand are under consideration in the instant application.

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-22,32 and 33 stand rejected under 35 U.S.C. 102(b) as being anticipated by WO 94/11027 for the same reasons set forth in the previous Office Action mailed on 03/11/10.

Applicant's arguments, filed 06/11/10 have been fully considered, but have not been found convincing.

Art Unit: 1644

Applicant asserts that WO' 027 does not disclosed the step of detecting an altered level of adhesion of cells to the target tissue, but rather disclosed detecting peripheralization. Applicant further asserts that WO' 027 only disclosed bone marrow endothelial tissue.

It is noted that the instant specification does not provide a clear definition for the term “detecting an altered levels of adhesion”.

It is well settled that during patent examination, the pending claims must be "given the broadest reasonable interpretation consistent with the specification." Thus, when the phrase “detecting an altered levels of adhesion” is given its broadest reasonable interpretation in light of specification, it can read on detecting peripheralization as taught by WO' 027

Moreover, as has been stated previously, WO' 027 does not limited its method only to bone marrow endothelial tissue. WO'027 teaches the general concept of altering the level of hematopoietic progenitor cell adhesion to target tissue. In particular, WO' 027 teaches that administering a blocking agent of VLA-4 antigen on the surface of hematopoietic stem cells and target tissue would result in disruption of interaction between VLA-4 and its microenvironmental ligand, such as fibronectin and/or VCAM-1 on stromal cell or in the extracellular matrix. Said blocking agent will act by competing with the extracellular matrix or stromal cell -bound binding protein for VLA-4 on the surface of stem cells. The proposed method comprises administering said blocking agent into the patient. (see pages 12, 15 and 25 in particular). In other word, said administration would inherently result in treating various target tissue that expressed integrin $\alpha 4\beta 1$ ligand. Mere recognition of latent properties in the prior art does not render nonobvious an otherwise known invention. In re Wiseman, 201 USPQ 658 (CCPA 1979). Granting a patent on the discovery of an unknown but inherent function would remove from the public that which is in the public domain by virtue of its inclusion in, or obviousness from, the prior art. In re Baxter Travenol Labs, 21 USPQ2d 1281 (Fed. Cir. 1991). See M.P.E.P. 2145.

The teaching of bone marrow endothelial tissue as a target tissue in WO'027 was a preferred embodiment, however, it is well settled that according to MPEP § 2123, “[d]isclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. In re Susi, 440 F.2d 442, 169 USPQ 423 (CCPA 1971). ‘A known or obvious composition does not become patentable simply because it has been described as somewhat inferior to some other product for the same use.’ In re Gurley, 27 F.3d 551, 554, 31 USPQ2d 1130, 1132 (Fed. Cir. 1994)...”

WO' 027 teaches a method for altering the levels of hematopoietic progenitor cell adhesion to target tissue comprising using an agent that alters specific binding of intergrin $\alpha 4\beta 1$ to an intergrin $\alpha 4\beta 1$ ligand (see entire document Abstract and pages 5,6, 12 in particular). WO' 027 teaches that said agent is an antibody, see pages 7 23 and 25 in particular).

The reference teaching anticipates the claimed invention.

Art Unit: 1644

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1-22, 32 and 33 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a New Matter rejection.**

“detecting altered level of HPC adhesion” claimed in 1 represent a departure from the specification and the claims as originally filed. The passages pointed by the applicant do not provide a clear support for “detecting altered level of HPC adhesion”. In particular, Applicant pointed to the Specification on page 68 and Example 10. However, that said passage referring to the use of $\alpha 44\beta 1$ antibodies to alter adhesion of EPC to vascular endothelial, not HPC. Moreover, it is noted that the Examiner withdrawn prior rejection under 35 U.S.C. 102(e) over WO’03/019136 because of Applicant’s statement that WO’03/019136 referring to EPC that are not HPC. (see Applicant’s comment, mailed on 11/16/09).

The specification and the claims as originally filed only support “The method for altering the level of HPC adhesion to target tissue”

7. No claim is allowed.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michail Belyavskiy whose telephone number is 571/272-0840. The examiner can normally be reached Monday through Friday from 9:00 AM to 5:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on 571/ 272-0735

The fax number for the organization where this application or proceeding is assigned is 571/273-8300

Art Unit: 1644

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Michail A Belyavskyi/
Primary Examiner, Art Unit 1644